

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS AND AMENDMENTS**

Claims 1-19 were pending in this application when last examined.

Claims 1-4, 7-9, 17 and 18 were examined on the merits and stand rejected.

Claims 5-6, 10-16 and 19 were withdrawn as non-elected subject matter.

Claim 4 has been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a divisional or continuation application on any cancelled subject matter.

Claim 1 has been amended to delete the non-elected subject matter and to include the nucleotide sequence which encodes the amino acid sequence of SEQ ID NO: 5. Support can be found in the disclosure, for example, at page 20, lines 13-18 and original claim 13.

Claim 2 has been amended into "comprising" format to better conform with U.S. practice. Claim 2 has also been amended to delete reference to the non-elected subject matter. Support for these changes can be found in original claim 2. Claim 2 has further been amended to specify the high stringent conditions for hybridization as supported by the disclosure at page 31, lines 1-8.

Claim 7 has been amended to provide proper punctuation by adding a comma before "which" in line 2. Support can be found in the claim as filed.

Claim 8 has been amended to delete reference to the non-elected subject matter. Claim 8 has also been amended to specify that the agent is useful for the diagnosis of cancer. Support can be found in original claim 8 and the abstract.

Claim 9 has also been amended to delete reference to the non-elected subject matter. Claim 9 has also been revised to specify that the agent is useful for the treatment of cancer. Support can be found in original claim 9 and the abstract.

Claim 17 has been amended into "comprises" format. Support can be found in the claim as filed.

Claim 18 has been amended to recite “the recombinant vector according to claim 17” to provide proper antecedent basis for the vector. Support can be found in original claims 17 and 18.

Therefore, no new matter has been added by this amendment to the claims.

Claims 1-3 and 5-19 are pending upon entry of this amendment.

## **II. OBJECTIONS TO THE SPECIFICATION**

In item 9 on page 1 and in items 2-3(b) on page 3 of the Office Action, the specification and Abstract were objected to for containing minor informalities.

It is respectfully submitted that the present amendment overcomes these objections.

The Abstract was objected to on the basis that it is more than one paragraph in length and exceeds 150 words. The Abstract has been revised into the proper format to comply with U.S. practice.

The specification has been amended to update the continuation data as requested by the Examiner.

In item 3(b), the title of the invention was objected to on the basis that it is not descriptive. The title has been revised to “POLYNUCLEOTIDE ENCODING THE hOT7T175 G PROTEIN COUPLED RECEPTOR” as suggested by the Examiner.

Therefore, the above-noted objections are untenable and should be withdrawn.

## **III. OBJECTION TO THE DRAWINGS**

In item 10 on page 1 and in item 1 on pages 2-3 of the Office Action, the disclosure and drawings were objected to on the basis that Figures 1-3 and 5-7 show sequences, which are not identified by SEQ ID NOS.

Please note that the corresponding Brief Description of the Drawings was previously amended to include the appropriate sequence identifiers for Figures 1-3 and 5-7 in the

Preliminary Amendment filed February 5, 2004 in accordance with U.S. practice. Therefore, it is unnecessary to revise the drawings to include the sequence identifiers.

Therefore, the objection is untenable and should be withdrawn.

#### **IV. OBJECTIONS TO THE CLAIMS**

In item 4(a) on page 4 of the Action, claims 1-2, 4 and 8-9 were objected to for reciting non-elected subject matter. The claims have been amended to delete the non-elected subject matter.

In item 4(b), claim 4 was objected to on the basis that it is improper for failing to further limit the subject matter of a previous claim. Claim 4 has been cancelled.

Thus, the above-noted claim objections are untenable and should be withdrawn.

#### **V. ENABLEMENT REJECTION**

In item 5 on pages 4-8 of the Office Action, claims 1-4, 7-9 and 17-18 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that while the specification is enabling for an isolated polynucleotide comprising the nucleic acid sequence of SEQ ID NO: 6 and an isolated polynucleotide comprising the nucleic acid sequence which encodes the polypeptide sequence of SEQ ID NO: 5, it does not reasonably provide enablement for an isolated polynucleotide which contains a base sequence identical to or at least 95% homologous to that represented by SEQ ID NO: 6. It is further indicated that the specification also does not reasonably provide enablement for an isolated polynucleotide which hybridizes to a base sequence represented by SEQ ID NO: 6 of claim 2.

This rejection is respectfully traversed as applied to the amended claims.

Amended claim 1 is directed to an isolated polynucleotide comprising a nucleotide sequence selected from the group consisting of the nucleotide sequence of SEQ ID NO: 6 and a nucleotide sequence which encodes the amino acid sequence of SEQ ID NO: 5. In other words, the polynucleotide of claim 1 has been amended to the full length sequence of SEQ ID NO: 6.

Accordingly, claim 1 has been amended to the subject matter indicated as enabled by the Examiner.

Amended claim 2 is directed to an isolated polynucleotide comprising a nucleotide sequence which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6 wherein the high stringent conditions comprise a sodium concentration at about 19 mM and a temperature at about 65 °C. Support for the high stringent conditions can be found in the disclosure at page 31, lines 1-8.

It is respectfully submitted that hybridization techniques and procedures are common and well known in the biotech industry. Furthermore, it is well established in the art that the term stringent conditions refers to hybridization and washing under conditions that permit only binding of a nucleic acid molecule, such as an oligonucleotide or cDNA molecule probe, to highly homologous sequences. Accordingly, sequences that hybridize under stringent conditions are limited to those sequences that form the requisite number of base pairs over the hybridized nucleotide sequences. Such nucleotide sequences will be structurally similar to the hybridized sequence.

Furthermore, it is well established in the art that the test of enablement is whether one reasonably skilled in the art can make or use the invention based on the disclosure in the specification coupled with the knowledge in the art without undue experimentation. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. The test is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. In fact, the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. See M.P.E.P. § 2164.01.

Again, it is respectfully submitted that the hybridization techniques and procedures are common and well known in the biotech industry. As such, it would require only routine

experimentation for the skilled artisan to isolate DNA sequences that hybridize under the highly stringent conditions as recited in the claims.

Furthermore, in item 6 on page 7 of the Action, claims 8-9 were rejected for the claim language “diagnosis of diseases associated with expression of the polypeptide and for the treatment of diseases associated with expression of the polypeptide and for the treatment of diseases associated with expression on the polypeptide.”

Kindly note that claims 8 and 9 have been limited to diseases associated with dysfunction of the receptor to cancer due to *in vivo* cancer metastasis suppressing activity as described in the disclosure at page 90, line 33 to page 91, line 7.

Moreover, it is respectfully submitted that these claims have been amended to the subject matter indicated as enabled by the Examiner. In this regard, at page 7, lines 12-14 of the Office Action, it was indicated that “undue experimentation will be required of the skilled artisan to determine a nexus between hOT7T175 expression and all possible diseases, other than cancer.” In reply, kindly note that the claims have been limited to cancer. As such, the claims have been amended to the subject matter indicated as enabled by the Examiner.

Therefore, the rejection of claims 1-4, 7-9 and 17-18 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

## **VI. WRITTEN DESCRIPTION REJECTION**

In item 7 on pages 8-11 of the Office Action, claims 1-4, 7-9 and 17-18 were rejected under 35 U.S.C. § 112, first paragraph, as lacking written description support for the claimed invention.

On page 9, it was indicated that the claim language “a base sequence represented by SEQ ID NO” was interpreted to include variants and derivatives.

This rejection is respectfully traversed as applied to the amended claims.

Kindly note that the polynucleotide of claim 1 has been amended to the full length sequence of SEQ ID NO: 6. In addition, the claim has been amended to include the high

stringent conditions for hybridization as disclosed at page 31, lines 1-8 of the disclosure. Also, the claim language “a base sequence represented by SEQ ID NO” has been replaced with “a nucleotide sequence of SEQ ID NO.” In view of these amendments, it is respectfully submitted that the claims have been amended to the subject matter indicated by the Examiner to be supported by the disclosure.

Therefore, the rejection of claims 1-4, 7-9 and 17-18 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

## **VII. INDEFINITENESS REJECTION**

In items 8-9 on page 11, claims 1, 3-4, 7-9 and 17-18 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the phrases “which contains” or “containing”.

This rejection is respectfully traversed as applied to the amended claims.

Kindly note that claims 1, 8, 9 and 17 have been amended to replace the phrases “which contains” or “containing” with “which comprises” or “comprising.” The amended language better conforms with U.S. practice and is well established and accepted in the art. Accordingly, one of skill in the art would understand the metes and bounds of such language.

Therefore, the rejection of claims 1, 3-4, 7-9 and 17-18 under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

## **VIII. ANTICIPATION REJECTIONS**

In item 10 on page 12, claim 2 was rejected under 35 U.S.C. § 102(b) as anticipated by Bell (US 5,436,155).

In item 11 on page 12, claims 1-4, 8-9 and 17-18 were rejected under 35 U.S.C. § 102(e) as anticipated by Borowsky (US 20020077469) (priority to 3/10/1999).

These rejections are respectfully traversed as applied to the amended claims.

To anticipate a claim, a cited prior art reference must teach each and every element of the claimed invention. See M.P.E.P. § 2131.01.

With regard to the 102(b) rejection over Bell, kindly note that amended claim 1 now requires a nucleotide sequence, which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6, wherein the high stringent conditions comprise a sodium concentration at about 19 mM and a temperature at about 65°C.

It is respectfully submitted that these hybridization conditions exclude the isolated nucleotide sequence in Bell having 14.6% identity to the nucleotide sequence of SEQ ID NO: 6. Attached herewith is page 6.58 of "Molecular Cloning: A Laboratory Manual", 3rd Edition, 2000 by Cole Spring Harbor Laboratory Press, Cold Spring Harbor, New York, in support of this position. As disclosed therein, members of a gene family from a single species or orthologous genes from different species can almost always be isolated by low stringency hybridization if they share 65% or greater sequence identity. Based on this disclosure, one of skill in the art would understand that the hybridization conditions defined in amended claim 2 do not detect the isolated nucleotide sequence in Bell having 14.6% identity to the nucleotide sequence of SEQ ID NO: 6.

Therefore, Bell fails to disclose or suggest each and every element of the claimed invention. Consequently, Bell cannot anticipate the claimed invention.

In response to the 102(e) rejection over Borowsky (US 20020077469) (priority to 3/10/1999), enclosed herewith is a verified English translation of the foreign priority document, Japanese Patent Application No. H11-027710, filed February 4, 1999. This document discloses the polynucleotide having the nucleotide sequence of SEQ ID NO: 6.

Pursuant to US practice, the submission of this translation removes Borowsky (US 20020077469) as 102(e) prior art, thereby obviating this rejection.

Therefore, the above-noted 102(b) and 102(e) rejections are untenable and should be withdrawn.

With regard to the 102(b) rejection over Bell, kindly note that amended claim 1 now requires a nucleotide sequence, which hybridizes under high stringent conditions to the nucleotide sequence of SEQ ID NO: 6, wherein the high stringent conditions comprise a sodium concentration at about 19 mM and a temperature at about 65°C.

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Pursuant to US practice, the submission of the translation removes the 102(e) rejection.

Therefore, the above-noted 102(b) and 102(e) rejections are untenable and should be withdrawn.




**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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**ATTACHMENTS**

1. "Molecular Cloning: A Laboratory Manual", 3rd Edition, 2000 by Cole Spring Harbor Laboratory Press, Cold Spring Harbor, New York;
2. English translation of the priority document, Japanese Patent Application No. H11-027710, filed February 4, 1999; and
3. Revised Abstract (clean version).